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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ZENECA
1800 Concord Pike
Wilmington, DE 19897

Attention: Mr. S.K. Theodorakis

Subject: WeatherBlok Bait With Bitrex
EPA Reg. No. 10182-339
Your amended application of July 16, 1996
Your letter of October 31, 1996

In the above submissions you submitted I) a revised Confidential Statement of Formula (CSF) and associated product chemistry (MRID Nos. 440634-01 thru -03) and efficacy data (MRID Nos. 440634-04 and -05) and II) a revised label. We have reviewed these documents and have the following comments.

I. Revised Confidential Statement of Formula (CSF) and Associated Product Chemistry and Efficacy Data

A. Product Chemistry Data

These data are acceptable.

B. Efficacy Data

We have reviewed the proposed revised confidential statement of formula (CSF of 7/16/96) submitted for this product on October 31, 1996, and the efficacy reports which were submitted to support this proposed formulation change. As the results of the efficacy studies meet or exceed the respective mortality criteria for fresh and weathered baits, we are in a position to accept these data and the proposed formulation change. Before doing so, however, I would like to attempt to persuade you to retain the product's current formulation.

The proposed new formulation differs from the product's current formulation largely through the addition of two purported "attractant" substances. Presumably, these substances were added in an attempt to make the product more attractive to target rodents and, therefore, more likely to be meet criteria in efficacy trials involving only one day of exposure to the bait. The proposed new formulation did meet the performance criteria for a one-day test, but did so only by "the skin of its teeth" for the house mice and was accepted well below the 33% criterion which would have applied to the fresh bait in a test of longer duration. As can be seen in the attached table (Table 9 taken from the efficacy review of the submissions addressed by this letter), the proposed new formulation was not accepted as well as the current formulation was in efficacy trials conducted and reviewed some time ago. Even if only the Day-1 acceptance data from the trials on the current formulation are considered, it is apparent that the new formulation was not as well accepted as the current formulation and was especially poorly attractive to house mice. Although the tests involving the two formulations were conducted years apart at different facilities and involved different housing conditions and different strains of laboratory rodents, it has been our experience that these factors may have been less likely than the flavor of the bait to affect the results of a palatability study. It seems sufficiently clear to us that the proposed formulation changes would not make this bait more attractive to commensal rodents than is the current formulation.

Because it appears that the current formulation is more palatable to commensal rats and mice than is the proposed new formulation which has met or exceeded the 1-day efficacy criteria when offered in fresh and weathered conditions, we can infer that the current formulation could be expected also to meet or exceed these criteria in a 1-day test. Therefore, we conclude that we could accept the efficacy data submitted to support the new formulation (MRID# 440634-04 and 440634-05) for the limited purposes of persuading us that additional laboratory efficacy data are not needed to retain the single-feeding and weather-resistance claims on the label for 10182-339 under its current formulation.

Please reply to this letter indicating whether you would prefer to retain the current formulation for this product or to amend the formulation to that described by the CSF of 7/16/96. Pending your reply, the proposed revised CSF is not accepted at this time.

II. Revised Labeling

- A. The Agency is currently reviewing generic data in preparation for issuance of an Anticoagulant Reregistration Eligibility Decision (RED) Document later this year. As part of that effort, the RED Team will be reconsidering the text of current labeling for these products. Therefore, we will not make a decision about the following two requests, at the

present time, but will refer them to the RED team for consideration:

1. Delete of "Birds" from the "ENVIRONMENTAL HAZARDS" section.
2. Revision of "Physician's Note".

If your company has any supporting documents to support these changes, they should be submitted now so that the RED Team will have the benefit of any such information.

- B. Currently, to conform to PR Notices 93-3 and 93-8, your "ENVIRONMENTAL HAZARDS" should read:

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

- C. Comments on Efficacy Claims and Use Directions

1. Delete "Effective" from the proposed front-panel claim "For Effective Control of Commensal Rats and Mice". Use of the word "Effective" implies a favorable comparison of this product to other (implied to be "Ineffective") registered commensal rodenticide baits which are required to meet essentially the same efficacy standards as are required of this product. Therefore, we consider the proposed use of "Effective" to be a misleading implied claim of comparison to other pesticides.
2. Change "Anti-Coagulant" to "Anticoagulant" in the proposed front-panel claim "Second Generation Anti-Coagulant". This claim actually is redundant to the "Kills warfarin-resistant" claim, but this circumstance might not be known by all potential customers.
3. The proposed changes to the "DIRECTIONS FOR USE" are nearly acceptable. Rather than as proposed, however, the second sentence of the "USE RESTRICTIONS" subsection should read as indicated below.


"WeatherBlok Bait with Bitrex may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

Let us know if you still wish to amend the CSF of this product.

Because of labeling changes anticipated in the RED, you may wish to delay revision of this label now. However, if you want to make changes at this time, you should submit three (3) copies of revised labeling without bolding and strikeout. [A single copy of revised labeling with the bolding and strikeout would be acceptable as a working copy. However, we will not stamp that version as it might be confusing to a person unfamiliar with the practice.]

If you have questions about this letter, please contact Mr. Dan Peacock at 703-305-5407.

Sincerely yours,


William W. Jacobs, PhD
Product Manager (14)
Insecticide-Rodenticide Branch
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